

Atty Dkt. No.: CLON-094
USSN: 10/806,930

REMARKS

In view of the following remarks, the Examiner is respectfully requested to withdraw the rejections and allow Claims 1-10 and 17-26, the only claims pending and currently under examination in this application.

Formal Matters

Claims 1-10 and 17-26 are pending after entry of the amendments set forth herein.

Claims 1-10 and 17-26 were examined. Claims 1-10 and 17-26 were rejected. No claims were allowed.

Claim 16 has been canceled as being directed to withdrawn subject matter.

Claims 1, 3, and 19 have been amended. Support for the amendment of Claim 1 can be found in the specification at, for example, page 9, lines 9 to 18. Claims 3 and 19 have been amended to remove objectionable language.

As the above amendments introduce no new matter to the application, their entry is respectfully requested.

Withdrawal of Objections

The Applicants express gratitude in the Examiner's indication that objections a not repeated from the Office Action dated December 23, 2004, have been withdrawn.

Priority

The Office Action maintains that the provisional applications 60/356,225, 60/383,336 and the non-provisional application 09/976,673 do not provide support for nucleic acid molecules encoding a polypeptide product comprising a first and second chromo/fluorescent domain that are form Cnidarian species. In particular, the Office Action asserts that "nowhere in the mentioned applications is there a statement regarding the fact that the sequence encodes proteins from Cnidarian species" (Office Action, page 2). Moreover, the Office Action notes that priority is only granted to international application PCT/US02/32560.

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The Applicants maintain that in addition to international application PCT/US02/32560, the provisional applications 60/356,225, 60/383,336, and the non-provisional application 09/976,673, all disclose a nucleic acid encoding a polypeptide product comprising a first and a second chromo/fluorescent domain, where the nucleic acid coding elements are from *Cnidarian* species. A detailed analysis is provided below with respect to each priority documents for the Examiner's convenience.

Non-Provisional Application 09/976,673

Non-provisional application 09/976,673 provides on page 40, lines 18-23, and Figures 12 and 3, a working example describing a nucleic acid encoding the polypeptide Cr-44-9. The Cr-44-9 polypeptide comprises a first and a second chromo/fluorescent domain as required by Claim 1 of the present application. Moreover, as noted on page 19, lines 17 to 23, the chromo/fluorescent domains are derived from *Heteractis crispa*, which is a *Cnidarian* species.

As shown in Figure 12, nucleic acid residues 1 to 697 of SEQ ID NO:15 encode the first chromo/fluorescent domain derived from *Heteractis crispa* (corresponding to amino acids residues 1 to 228 of SEQ ID NO:16), and nucleic acid residues 710 to 1396 of SEQ ID NO:15 encode the second chromo/fluorescent domain derived from *Heteractis crispa* (corresponding to amino acids residues 233 to 460 of SEQ ID NO:16). Accordingly, the Cr-44-9 polypeptide comprises a first and a second chromo/fluorescent domain as required by Claim 1 of the present application

Provisional Application 60/356,225

The Applicants note that the provisional application 60/356,225 provides support for the nucleic acids on page 3, lines 1 to 9, which recites the following:

The subject invention provides nucleic acids encoding a polypeptide product comprising a first and second chromo/fluorescent domain, optionally joined by a linking domain, wherein the first and second chromo/fluorescent domains associate with each other under intracellular conditions so that the encoded polypeptide assumes a tertiary structure. In certain embodiments, the first and second chromo/fluorescent domains

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are oligomeric producing domains. In certain embodiments, chromo/fluorescent domains are chromo-or fluorescent proteins from a Cnidarian species or mutants of chromo-or fluorescent proteins from a Cnidarian species.

(emphasis added).

Moreover, the provisional application 60/356,225 also provides on page 34, line 30 through page 35, line 8, and Figure 1, a working example describing a nucleic acid encoding Cr-44-9. The Cr-44-9 polypeptide includes a first and second chromo/fluorescent domain from a Cnidarian species.

Provisional Application 60/383,336

Provisional application 60/383,336 also provides support for the nucleic acids on page 4, lines 23 to 31, which recites the following:

In certain embodiments, the first and second chromo/fluorescent domains are oligomeric producing domains. In certain embodiments, chromo/fluorescent domains are chromo-or fluorescent proteins from a Cnidarian species or mutants of chromo-or fluorescent proteins from a Cnidarian species. In certain embodiments, the Cnidarian species is a non-bioluminescent Cnidarian species, e.g., a non-bioluminescent Cnidarian species is an Anthozoan species. In certain embodiments, the nucleic acid encodes a fusion protein of the first and second chromo/fluorescent domains fused to a non-chromo/fluorescent protein domain.

(emphasis added).

Furthermore, the provisional application 60/383,336 also provides on page 34, line 30 through page 41, lines 18-30, and Figures 1 and 3, a working example describing a nucleic acid encoding Cr-44-9 and a nucleic acid encoding HcRed-cr-1. The Cr-44-9 polypeptide includes a first and second chromo/fluorescent domain from a Cnidarian species. In addition, the HcRed-cr-1 polypeptide includes a first and second chromo/fluorescent domain from a Cnidarian species.

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Therefore, it is respectfully submitted that the Applicants are entitled to an earliest priority date of October 12, 2001, the filing date of non-provisional application 09/976,673.

Rejection under 35 U.S.C. § 112, first paragraph (Written Description)

The Office Action has maintained the rejection of Claims 3-4 and 19-21 under 35 U.S.C. § 112, first paragraph, for allegedly lacking written description. In the spirit of expediting prosecution and without conceding as to the correctness of the rejection, Claims 3 and 19 have been amended to remove the objectionable language. Accordingly, this rejection may be withdrawn.

Rejection Under 35 U.S.C. § 102

The Office Action has maintained the rejection of Claims 1-10 and 17-26 under 35 U.S.C. § 102(b) for allegedly being anticipated by Lukyanov et al., WO 01/27150 ("Lukyanov et al."). This rejection is respectfully traversed.

The Applicants note that while the Office Action rejects Claims 1-10 and 17-26 under U.S.C. § 102(b), the more appropriate rejection is under 35 U.S.C. § 102(a). In particular, Lukyanov et al. was not published more than one year prior to the earliest priority date of the present application. Lukyanov et al. was published on April 19, 2001, and, as noted in greater detail above, the earliest priority date of the present application is October 12, 2001. Accordingly, since Lukyanov et al. was published less than one year prior to the earliest priority date of the present application, the cited reference is only available as art under 35 U.S.C. § 102(a).

In maintaining the rejection, the Office Action cites page 9, lines 29 to 34 of Lukyanov et al., which provides a general discussion of fusion proteins comprising the chromo/fluoroprotein mutants. However, the cited passage does not teach a polypeptide product comprising a first chromo/fluorescent domain and a second chromo/fluorescent domain.

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The Office Action further cites page 14, lines 36-37, which provides a general discussion of protein folding in host cells. However, the cited passage does not teach polypeptide product comprising a first and second chromo/fluorescent domain, wherein the first and second chromo/fluorescent domains oligomerize under intracellular conditions so that the polypeptide assumes a tertiary structure.

In the spirit of providing clarity to the claims and without conceding to the correctness of the rejection, Claim 1 has been amended to recite "wherein said first and second chromo/fluorescent domains oligomerize under intracellular conditions so that said encoded polypeptide assumes a tertiary structure".

Lukyanov et al. fails to teach nucleic acids encoding polypeptides comprising a first chromo/fluorescent domain and second chromo/fluorescent domain, wherein the first and second domains oligomerize with each other under intracellular conditions. Therefore the cited reference fails to disclose every element found in the claims of the present invention. As such, Claims 1-10 and 17-26 are not anticipated by the cited reference, and this rejection may be withdrawn.

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CONCLUSION

In view of the above remarks, this application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issuance.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815.

Respectfully submitted,
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